

REMARKS

The Present Invention

The present invention is directed to an adenoviral vector comprising an adenovirus serotype 5 genome and comprising a nucleic acid sequence encoding pigment epithelium-derived factor (PEDF) or a therapeutic fragment thereof, wherein the nucleic acid sequence is operably linked to a CMV promoter, the adenoviral vector is rendered replication deficient by deletion of all of the E1 region and deletion of a portion of the E4 region, and the adenoviral vector comprises a pGUS spacer sequence in place of the deleted portion of the E4 region.

The Pending Claims

Claims 1, 8, 11-14, and 18-21, 24-27, and 45 are pending. All of the pending claims are directed to the adenoviral vector described above.

The Amendments to the Claims

Claim 1 has been amended to more clearly define the deficiencies that render the adenoviral vector replication deficient. Specifically, claim 1 has been amended to recite that the adenoviral vector is rendered replication deficient by deletion of all of the E1 region and by deletion of a portion of the E4 region. This amendment is supported by the specification at, for example, page 6, lines 27-32, and page 7, lines 8-10. Claim 1 also has been amended to recite that the adenoviral vector comprises a pGUS spacer sequence in place of the deleted portion of the E4 region. This amendment is supported by, for example, the second paragraph of the text added to the specification in the "Response to Office Action" dated December 10, 2003. Claim 47 is new and is supported by the specification at, for example, page 14, lines 12-16, and Example 2. Claims 22 and 23 have been cancelled as being drawn to a non-elected invention. Accordingly, no new matter has been added by way of these claim amendments. Applicants reserve the right to pursue any cancelled subject matter in a continuation, continuation-in-part, divisional, or other application. Cancellation of any subject matter should not be construed as abandonment of that subject matter.

The Office Action

The Office Action requires cancellation of claims 22 and 23 as being drawn to a non-elected invention. The Office Action objects to the amendment to the specification made in the "Response to Office Action" dated December 10, 2003 under 35 U.S.C. § 132 as allegedly introducing new matter into the specification. Claims 1, 8, 11-14, 18-21, and 24-27

are rejected under 35 U.S.C. § 112, first paragraph for an alleged lack of written description. Claims 1, 8, 11-14, 18-21, and 24-27 also are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Reconsideration of these rejections is hereby requested.

Discussion of Objection under 35 U.S.C. § 132

The Office Action has rejected the amendment to the specification made in the “Response to Office Action” dated December 10, 2003. Specifically, the Office Action contends that Applicants did not file an affidavit or declaration stating that the amendatory material consists of the same material incorporated by reference in the referencing application. Submitted herewith is a declaration to that effect executed by Applicants’ representative Heather R. Kissling.

The Office Action further alleges that the sentence beginning “[t]he present inventive adenoviral vector...” in the incorporated text constitutes new matter because it refers to the adenoviral vector of U.S. Patent 5,851,806 (“the ‘806 patent”), and not the adenoviral vector of the subject application. Applicants note that, when the content of a document is incorporated by reference in the text of an application, the information incorporated is as much a part of the application as filed as if the text of the document was repeated in the application, and should be treated as part of the text of the application as filed. Moreover, replacing the identified material incorporated by reference with the actual text is not new matter. M.P.E.P. § 2163.07(b). The subject application indicates at page 7, lines 2-4, that suitable adenoviral vectors for use in the claimed invention are disclosed in the ‘806 patent. The subject application further indicates at page 22, lines 1-3 that “all references cited herein are hereby incorporated by reference to the same extent as if each reference was individually and specifically indicated to be incorporated by reference and was set forth in its entirety herein.” Thus, the text of the ‘806 patent that was added to the specification in the “Response to Office Action” dated December 10, 2004, should be treated as part of the text of the application as filed, and the sentence beginning “[t]he present inventive adenoviral vector...” should be construed as referring to the adenoviral vector of the subject application. Accordingly, the objection under 35 U.S.C. § 132 is improper and should be withdrawn.

Discussion of Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1, 8, 11-14, 18-21, and 24-27 have been rejected under Section 112, first paragraph, for an alleged lack of written description. This rejection is respectfully traversed for the reasons set forth below.

The Office Action contends that Applicants cited different sections of the subject application and of the '806 patent as support for the amendment to claim 1 made in the "Response to Office Action" dated December 10, 2003, and that these sections do not provide support for the amendment. In particular, the Office Action alleges that parts of the vectors disclosed in '806 patent (e.g., an adenoviral vector comprising a pGUS spacer in the E4 region) cannot be directly combined in any manner with the specification of the subject application, because there is no support for "mixing and matching" components of the vectors disclosed in each document.

As discussed above, information incorporated by reference into a patent application is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Thus, the text of the '806 patent that was added to the specification in the "Response to Office Action" dated December 10, 2004, is to be treated as part of the text of the application as filed. In other words, the disclosure of an adenoviral vector comprising a spacer (e.g., a pGUS spacer) inserted into a deleted E4 region of the adenoviral genome should be treated as a description of the invention, irrespective of the source of that disclosure. In addition, the text of the '806 patent added to the subject application refers to an "E4" adenoviral vector" and states that the spacer can be inserted into the E4 region.

Thus, the subject matter of the pending claims is described in such a way as to reasonably convey to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time the subject application was filed. Accordingly, the Section 112, first paragraph, rejection is improper and should be withdrawn.

Discussion of Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1, 8, 11-14, 18-21, and 24-27 have been rejected under Section 112, second paragraph, as allegedly being indefinite. This rejection is traversed for the reasons set forth below.

The Office Action alleges that the phrase "deletion of all of the E1 region and all of the E4 region, and (c) the adenoviral vector comprises a pGUS spacer in the E4 region" in claim 1 renders that claim indefinite because it is unclear how the pGUS spacer can be in the E4 region when the entire E4 region is deleted. In order to advance prosecution of the subject application, and not in acquiescence of the rejection, claim 1 has been amended to recite that the adenoviral vector comprises a pGUS spacer *in place of* the deleted portion of the E4 region. Thus, one of ordinary skill in the art would understand the metes and bounds of claim

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1, and claims 8, 11-14, 18-21, 24-27, and 47 depending therefrom. Accordingly, the Section 112, second paragraph, rejection should be withdrawn.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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Date: May 12, 2004



PATENT
Attorney Docket No. 204526

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kovesdi et al.

Art Unit: 1636

Application No. 09/599,997

Examiner: T.A. McKelvey

Filed: June 23, 2000

For: VIRAL VECTOR ENCODING
PIGMENT EPITHELIUM-DERIVED
FACTOR

DECLARATION OF HEATHER R. KISSLING

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

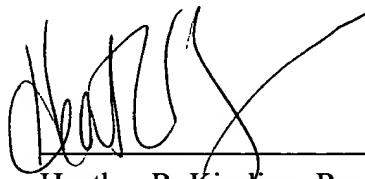
Dear Sir:

1. I am one of the registered patent agents working for the Applicants.
2. A "Response to Office Action" in the subject application was filed with the U.S. Patent and Trademark Office on December 10, 2003.
3. The "Response to Office Action" filed on December 10, 2003, amended the specification to include text from U.S. Patent 5,851,806 ("the '806 patent"), the disclosure of which was incorporated by reference into the subject application (see specification at page 6, lines 12-15, and page 7, lines 2-4).
4. The text added to the subject application by way of the "Response to Office Action" dated December 10, 2003, is identical to the text of the '806 patent incorporated by reference in the subject application.
5. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like

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so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2/2/04



Heather R. Kissling, Reg. No., 45,790